

VALLEY FORGE SCIENTIFIC CORPORATION

July 25, 1985

Food and Drug Administration
Office of Device Evaluation
Document Control Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

RE: 510 (k) Notification

Attention: Document Mail Center

Valley Forge Scientific Corporation wishes to notify you of its intention to manufacture and sell a Malis Bipolar Pen which is a hand-held electrosurgical tool used to coagulate very small blood vessels during surgery. The device is actually a coaxial electrode similar in use to the Bovie type electrosurgical pens which have been marketed for the past 20-25 years (prior to May 28, 1976). The Malis Bipolar Pen is essentially identical to the Mentor Wet-Field hemostatic eraser. All of these devices are connected to an electrosurgical generator via a monopolar or bipolar cord.



Here is a list of the information you will need:

- A. Classification Name: Electrosurgical Coagulation
Common/Usual Name: Electrosurgical Pen or Pencil
Proprietary Name: Malis Bipolar Pen
- B. Establishment Registration Number: 2521567.
- C. Classification: Either Electrosurgical Coagulation and cutting Devices under Class II with the Classification Panel being 79 GEI
or
Coagulation Probe, 84GXI.
- D. Performance Standard: None established under Section 514.
- E. Draft copy of proposed labeling/promotional material are attached as Exhibit I.

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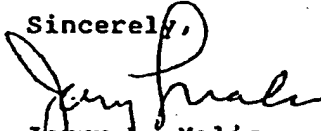
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F. Substantial Equivalence: The Malis Bipolar Pen is substantially equivalent in function and design to the Bovie-type pens/pencils as marketed by Sybron, Valleylab, Aspen Labs, Birtcher, Olsen, Mentor and other electrosurgical manufacturers. A sampling of literature for these units is attached and marked as Exhibits II-VI.

All of our electrosurgical products (generators and accessories) are manufactured in accordance with the applicable GMP Rules and Regulations under Part 820 of the Federal Food, Drug, and Cosmetic Act as amended October 1976. We anticipate marketing the Malis Bipolar Pen through two Johnson and Johnson Companies: SITE Microsurgical Systems, Inc. and Codman & Shurtleff, Inc.

If you require any further information, please call me at (215) 631-1050.

Sincerely,



Jerry L. Malis
President

Enclosure

SN 61167